REMARKS

I. AMENDMENTS

Claims 1, 3-10 and 12-41 are currently pending in this application. Claims 1, 3-10, 12-16, 37 and 38 are under examination.

Claims 1 and 15 have been amended to indicate that the composition reduces the gastric toxicity associated with the NSAID compound. The Applicants aver that the amendments do not add new subject matter as support may be found throughout the Specification and at, for example, page 10, the last paragraph to page 12, paragraph 2; page 15, paragraph 3; page 20, the last paragraph, which extends to page 21; and page 27, the last paragraph of the application as filed.

Claims 6 and 16 have been amended to correct a much regretted typographical error in the naming of certain compounds. The Applicants aver that the amendments to thes claims do not add new subject matter as support may be found in the chemical structures provided in Figures 3C-E.

Claim 3-5 has been cancelled without prejudice. Applicants respectfully request reexamination and reconsideration of the application in light of the foregoing amendments and following remarks.

II. DOUBLE PATENTING

Claims 1, 3-10, 12-16, 37 and 38 stand rejected on the ground of non-statutory double patenting over the claims in the following patents or co-pending applications.

U.S. Patent Application No. 11/355,145;
U.S. Patent Application No. 11/355,306;
U.S. Patent Application No. 11/501,393;
U.S. Patent Application No. 11/636,867; and
U.S. Patent Application No. 12/063,039.

The Applicants accept the Examiner's determination and herein provide terminal disclaimers linking the above referenced cases to the instant case.

Claims 1, 3-10, 12-16, 37 and 38 stand rejected on the ground of non-statutory double patenting over the claims in the following patents or co-pending applications.

U.S. Patent Application No. 11/820,600;
U.S. Patent Application No. 11/820,755;
U.S. Patent Application No. 11/820,621;
U.S. Patent Application No. 11/820,608;
U.S. Patent Application No. 11/820,568;
U.S. Patent Application No. 11/820,607;
U.S. Patent Application No. 11/649,584
U.S. Patent Application No. 10/590,424; and
U.S. Patent Application No. 11/820,653.

The Applicants respectfully disagree in that the above referenced applications were filed after the filing date of the instant case and are properly the subject of non-statutory double patenting rejections. As such, the Applicants request withdrawal of the of non-statutory double patenting rejections vis-à-vis the previously cited applications.

Claims 1, 3-10, 12-16, 37 and 38 stand rejected on the ground of non-statutory double patenting over the claims in the following patents or co-pending applications. The Applicants respectfully disagree for the reasons cited below.

U.S. Patent Application No. 10/789817; U.S. Patent Application No.11/823934; U.S. Patent Application No. 10/590301; U.S. Patent Application No. 10/866315; U.S. Patent Application No. 10/532,388 and U.S. Patent Application No. 11/326874 fail to teach the use of combinations of reduced isoalpha acids, dihydro-isoalpha acids, tetra-hydroisoalpha acids, and hexa-hydroisoalpha acids and NSAIDS. NSAIDS are merely described and mentioned in the Background for their anti-inflammatory properties. As such, Applicants respectfully request withdrawal of these rejections.

III. CLAIM REJECTION UNDER 35 U.S.C. § 112

Claims 1, 3-5, 7-10, 13-15, 37 and 38 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner states that "[t]he claims are drawn to a composition comprising a resuced isoalpha acid, dihydro isoalpha acid, tetra hydro isoalpha acid or hexahydro isoalpha acid along with a NSAID (non-aspirin, non-steroidal anti-inflammatory). Thus, the claims are drawn to a genus of compounds which are not completely quantifiable." Office Action, page 13. Applicants respectfully traverse.

According to MPEP § 2163 II,3(a)(ii), the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

In the present application, Figure 2 illustrates the chemical structures of reduced isoalpha acids, dihydro isoalpha acids, tetra hydro isoalpha acids and hexahydro isoalpha acids. Figures 3C-3E further provide chemical structures of representative species of these compounds in which the "R" group may vary as described in the description of Figure 3, on page 7. The physical characteristics (e.g., derived from hops) and chemical properties (e.g., being in reduced form) of the genus and the representative species of the genus are further described on page 7, paragraph 2 to page 19, paragraph 2. The functional characteristic of these compounds as cyclooxygenase-2 (COX-2) inhibitors are also described throughout the application and at, for example, Example 3. The Examples further disclose correlation between function and structure for these compounds.

Having disclosed structure, function, and working examples that correlate the structure and function, the specification provides sufficient written description for a skilled artisan to predict the operability in the invention of any and all species of the of compounds selected from

the group consisting of reduced isoalpha acids, dihydro isoalpha acids, tetra hydro isoalpha acids and hexahydro isoalpha acids, other than the ones disclosed. As such, Applicants respectfully submit that they were in possession of the invention as claimed with respect to the genus of compounds selected from the group consisting of resuced isoalpha acids, dihydro isoalpha acids, tetra hydro isoalpha acids and hexahydro isoalpha acids.

As for the genus of non-aspirin, non-steroidal anti-inflammatory compounds (NSAIDs), without acquiescing to the reasoning offered in the Office Action, Applicants have amended claim 1 to include the specific NSAID species previously recited in claim 11.

As such, and based on the foregoing remarks, Applicants respectfully submit that they were in possession of the invention as claimed and request the withdrawal of this rejection.

IV. CLAIM REJECTION UNDER 35 U.S.C. § 103

Claims 1, 3-5, 7-10, 13-15, 37 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Khurts (US 20070003646) in view of Grattan (US 5866162). The Applicants respectfully disagree.

Claims 1 and 15 have been amended *supra* to teach that the composition of the invention inhibits the gastric toxicity from the associated NSAID. The Applicants maintain that Kuhrts fails to teach the use of NSAIDS nor how to reduce the gastric toxicity from NSAID use. This deficiency is not corrected by Grattan as Grattan describes an oral formulation for an anti-inflammatory but fails to address NSAID associated toxicity. The Applicants maintain that these failures do not render the instant invention obvious as they provide no basis to combine components to produce a composition with reduced gastric toxicity. As such, Applicants respectfully request withdrawal of the rejection of Claims 1, 3-5, 7-10, 13-15, 37 and 38 under 35 U.S.C. § 103(a).

V. CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's agent at the telephone number shown below.

The Commissioner for Patents is authorized to charge any fees required under 37 C.F.R. 1.20(d), for the terminal disclaimers filed herewith, to deposit account 50-1133.

A Request for a Three (3) Month Extension of Time, up to and including May 23, 2010, is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(3), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under paragraph 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

Dated: May 21, 2010

By: _____

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